

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION
Antimicrobial Division

3/29/2016

DP BARCODE: 431593

MRIDs: 497410-01

SUBJECT: XHC-E

REG. NO. OR FILE SYMBOL: 1677-254

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use product ☐ OR End-use product ☒

INGREDIENTS (PC Codes): 014703

CAS Number: 7681-52-9

TEST LAB:

SUBMITTER: Ecolab, Inc.

GUIDELINE:

COMMODITIES:

REVIEWER: Sergey Alekseyev

ORGANIZATION: AD/PSB/CTT

APPROVER: Karen P. Hicks

APPROVED DATE:

COMMENT:

From: Sergey Alekseyev, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

S. Alekseyev

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

*Chris Jiang
for KPH*

To: Demson Fuller/Ben Chambliss
PM Team 32

APPLICANT: Ecolab, Inc.

Action code: (A540) New Product; Non-Fast Track; FIFRA Sec. 2(MM) Uses

Formulation from Label

PC Code(s)	CAS #(s)	Active Ingredient Names	%wt (label)
014703	7681-52-9	Sodium hypochlorite	3.9

BACKGROUND:

Ecolab, Inc. provided EPA Form 8570-4 (Confidential Statement of Formula), a basic formulation, dated 10/13/2015; MRID No. 497410-01; a label, dated 10/28/2015; and EPA Form 8570-35 (Data Matrix), dated 10/30/2015. The registrant is requesting product chemistry review of the subject product.

FINDINGS:

1. EPA Reg. No. **1677-254** is an end-use product containing the active ingredient Sodium hypochlorite, with a label claim nominal concentration of 3.9%; and other ingredients content of 96.1%. The product is for cleaning of surfaces or medical devices and killing of germs. The product is produced by an integrated system.
2. The CSF for the basic formulation is not acceptable. The certified limits for the inert are acceptable in accordance with 40 CFR §158.350. All ingredients are cleared for use in pesticide formulations. However, the CSF contains flaws as follows:
 - a) Cell 4 does not contain the Reg. No. of the subject product.
 - b) The content of the active ingredient shown in cell 13b (0.58%) disagrees with that on the label (3.9%). The values of the lower and upper certified limits for the active ingredient are wrong, too.
3. Except for Finding 4, data reported in MRID No. 497410-01 satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.
4. Storage Stability and Corrosion Characteristics studies have been carried out after 4 weeks at 40 °C. Guidelines 830.6317 and 830-6320 require these studies to be carried out after 1 year at room temperature. Accelerated studies may be carried out after 2 weeks at 54 °C.
5. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 97-6. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSIONS:

The registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. **1677-254** after submission of a corrected CSF (see Finding 2) and upgraded studies pertinent to Storage Stability and Corrosion Characteristics (see Finding 4).

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	497410-01	Y
.1600 Description of Materials Used to Produce the Product	158.325	497410-01	Y
.1620 Description of Production Process	158.330	497410-01	Y
.1650 Discussion of Formulation Process	158.165		N/A
.1670 Discussion of Formation of Impurities	158.167	497410-01	Y
.1700 Preliminary Analysis	158.345		N/A
.1750 Certified Limits	158.350	497410-01	Y
.1800 Enforcement Analytical Method	158.355	497410-01	Y

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Clear, colorless	497410-01	Y
.6303 Physical State	Liquid	497410-01	Y
.6304 Odor	Faint chlorine odor	497410-01	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	Not applicable. The product is not TGAI/MP.		N/A
.6314 Oxidation/Reduction Chemical Incompatibility	The product is oxidizer.	497410-01	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	497410-01	N/A
.6316 Explodability	The product is not potentially explosive.	497410-01	Y
.6317 Storage Stability	The product is stable after 4 weeks at 40 °C.	497410-02	U
.6319 Miscibility	The product is not to be mixed with petroleum distillate.		N/A
.6320 Corrosion Characteristics	No signs of corrosion attack upon the package (HDPE) after 4 weeks at 40 °C.	497410-02	U
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	497410-01	N/A
.7000 pH	11.9	497410-01	Y
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	2.52 cPs		N/A
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.013	497410-01	Y
.7370 Dissociation Constant in Water	Not applicable. The product is not TGAI/MP.		N/A
.7550 Octanol/Water Partition Coefficient	Not applicable. The product is not TGAI/MP.		N/A
.7840 Solubility to Water and Organic Solvents	Not applicable. The product is not TGAI/MP.		N/A
.7950 Vapor Pressure	Not applicable. The product is not TGAI/MP.		N/A

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived